16 April 2019

SUMMARY REPORT
ICH MC TELECONFERENCE
25 March 2019

LIST OF PARTICIPANTS

ICH MC Members

Ms. Lila Feisee	BIO
Dr. Milton Bonelli	EC, Europe
Mr. Pär Tellner	EFPIA
Dr. Theresa Mullin *(Chair)*	FDA, United States
Dr. Celia Lourenco	Health Canada, Canada
Mr. Leo Bouthilier	Health Canada, Canada
Dr. Dorothy Toh	HSA, Singapore
Dr. Nick Cappuccino	IGBA
Ms. Beata Stepniewska	IGBA
Dr. Hironobu Hiyoshi	JPMA
Dr. Masafumi Yokota	JPMA
Ms. Kyung Won Seo	MFDS, Republic of Korea
Dr. Young-Ok Kim	MFDS, Republic of Korea
Dr. Nobumasa Nakashima *(MC Vice-Chair)*	MHLW/PMDA, Japan
Dr. Naoyuki Yasuda	MHLW/PMDA, Japan
Dr. Junko Sato	MHLW/PMDA, Japan
Mr. Siyuan Zhou	NMPA, China
Mr. Xiaoling Qin	NMPA, China
Dr. Peter Honig	PhRMA
Dr. Petra Doerr	Swissmedic, Switzerland

ICH MC Coordinators

Ms. Lila Feisee	BIO
Dr. Georgios Balkamos	EC, Europe
Ms. Giovanna Rizzetto	EFPIA
Ms. Amanda Roache	FDA, United States
Dr. Shinichiro Hirose	IGBA
Mr. Mitsuo Mihara	JPMA
Ms. Pan Soon Kim	MFDS, Republic of Korea
Mr. Fumihito Takanashi	MHLW/PMDA, Japan
Dr. Yang Wang	NMPA, China
Ms. Camille Jackson	PhRMA

ICH MC Technical Coordinators

Dr. Milton Bonelli	EC, Europe
Dr. Yasuhiro Kishioka	MHLW/PMDA, Japan

ICH MC Standing Observers

Ms. Sharon Olmstead	IFPMA
Mr. David Jefferys	IFPMA

Other Participants

Ms. Sayaka Kurihara	MHLW/PMDA, Japan

ICH Secretariat

Ms. Coralie Angulo
Dr. Anne Latrive
Ms. Nadia Myers Biggs
Dr. Dawn Ronan

SUMMARY REPORT

MC Chair: Dr. Theresa Mullin - FDA, United States

MC Vice-Chair: Dr. Nobumasa Nakashima - MHLW/PMDA, Japan

1. ADOPTION OF THE AGENDA

Dr. Theresa Mullin (MC Chair) welcomed all participants. The agenda was adopted without modification.

2. ORGANISATION OF THE AMSTERDAM MEETING

The MC was updated by the Secretariat on the organisation of the Amsterdam, the Netherlands meeting to be held in June 2019, including on the meeting registration process which had been initiated for Coordinators to validate their delegate lists. The MC was furthermore informed that the meeting venue could accommodate up to 15 Working Group (WG) meetings in parallel.

MC Actions/Decisions:

- *The MC noted the organisation of a Briefing Session for ICH experts on Monday, 3 June from 8h00 to 8h45, for presentation by the ICH Secretariat;*
- *The MC supported the draft overall timetable for the scheduling of the meetings of the Management Committee and the Assembly;*
- *The MC noted the following key dates in preparation of the Amsterdam meeting:*
  - *By **30 April**: The draft MC Agenda will be circulated to the MC for comments;*
  - *By **1 May**: All background documents for the Assembly meeting are to be provided to the Secretariat for MC review prior to inclusion in the Assembly Agenda paper;*
  - *By **8 May**: The draft Assembly Agenda will be circulated to the Assembly for comments;*
  - *By **13 May**: All background documents for the MC meeting are to be provided to the Secretariat for inclusion in the MC Agenda papers;*
  - ***By 22 May**: The Assembly Agenda papers will be circulated to the Assembly.*

3. PREPARATION OF AMSTERDAM: ORGANISATION OF WG MEETINGS

Summary table of MC decisions taken electronically and at the TC:

Summary table of MC decisions taken electronically and at the TC:List of Current 29 ICH Working Groups		**WGs with meeting requests for further consideration by the MC** (ref. section 3.1 of the report)	**WGs with meeting requests approved at the MC Technical TC on 25 March** (ref. section 3.1 of the report)	**WGs with meeting requests approved electronically by the MC on 12 March 2019** (ref. section 3.2 of the report)	**WGs not requesting to meet** (ref. section 3.3 of the report)
Efficacy Groups	Standing Paediatric EWG				x
	E2B(R3) EWG/IWG		x (4 days – Mon to Thu)		
	E8(R1) EWG		x (4 days – Sun to Wed)		

Summary table of MC decisions taken electronically and at the TC:List of Current 29 ICH Working Groups		**WGs with meeting requests for further consideration by the MC** (ref. section 3.1 of the report)	**WGs with meeting requests approved at the MC Technical TC on 25 March** (ref. section 3.1 of the report)	**WGs with meeting requests approved electronically by the MC on 12 March 2019** (ref. section 3.2 of the report)	**WGs not requesting to meet** (ref. section 3.3 of the report)
	E9(R1) EWG			x (4 days – Mon to Thu)	
	E11A EWG			x (4 days – Mon to Thu)	
	E14/S7B IWG			x (4 days – Mon to Thu)	
	E17 IWG		x (4 days – Mon to Wed)		
	E19 EWG				x
	E20 informal WG				x
Multidisciplinary Groups	M1 PtC WG				x
	M2 EWG		x (4 days – Mon to Thu)		
	M4Q(R1) IWG				x
	M7(R2) Maint. EWG/IWG			x (4 days – dates to be confirmed in coordination with Q3D(R2)[1])	
	M8 EWG/IWG				x
	M9 EWG		x (4 days – Mon to Thu)		
	M10 EWG				x
	M11 EWG			x (4 days – Mon to Thu)	
	M12 informal WG				x
Quality Groups	Q3C(R8) Maint. EWG				x
	Q3D(R2) Maint. EWG	x (2 days in coordination with the M7(R2)			

[1] Post teleconference note dated 29 March 2019: Further to the TC, the MC confirmed approval for the M7(R2) Maint. EWG/IWG meeting from Monday to Thursday.

Summary table of MC decisions taken electronically and at the TC:List of Current 29 ICH Working Groups		WGs with meeting requests for further consideration by the MC (ref. section 3.1 of the report)	WGs with meeting requests approved at the MC Technical TC on 25 March (ref. section 3.1 of the report)	WGs with meeting requests approved electronically by the MC on 12 March 2019 (ref. section 3.2 of the report)	WGs not requesting to meet (ref. section 3.3 of the report)
		meeting to be confirmed[2])			
	Q11 IWG				x
	Q12 EWG		(1 day - additional meeting on Saturday approved)	x (5 days – Sunday to Thursday)	
	Q2(R2)/Q14 EWG			x (4 days – Mon to Thu)	
	Q13 EWG			x (4 days – Mon to Thu)	
Safety Groups	S1(R1) EWG				x
	S5(R3) EWG			x (4 days – Mon to Thu)	
	S11 EWG		x (4 days – Mon to Thu)		
Discussion Groups	*IGDG*				x
	IQDG				x
TOTAL		**1**	**6**	**9**	**13**

[2] Post teleconference note dated 29 March 2019: Further to the TC, the MC confirmed approval for the Q3D(R2) Maint. EWG meeting from Thursday to Friday.

3.1. WGS REQUESTING TO MEET IN AMSTERDAM

3.1.1. M9 EWG: Biopharmaceutics Classification System-based Biowaivers *(Rapporteur: Dr. Welink – EC, Europe; Regulatory Chair: Dr. Seo – FDA, United States)*

Further to Assembly endorsement of Step 2a/b at the meeting in Kobe, Japan in June 2018, the M9 Draft Guideline underwent public regulatory consultation in the ICH Member regions until end of January 2019.

The MC noted the work plan of the M9 EWG and was updated by the Coordinator for EC, Europe on the progress made by the group on obtaining and compiling the comments received during the public regulatory consultation period; as well as on the group's considerations on the necessity to meet face-to-face in Amsterdam in June 2019.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Amsterdam in June 2019.*

Steps 3 and 4 are expected in June 2019.

3.1.2. Q3D(R2) Maintenance EWG: Maintenance of the Guideline for Elemental Impurities *(Rapporteur: Dr. McGovern – FDA, United States; Regulatory Chair: N/A)*

Further to Assembly endorsement of Step 2a/b in May 2018, the Q3D(R1) revision of the Cadmium Inhalation Permitted Daily Exposure (PDE) underwent public regulatory consultation in the ICH Member regions until November 2018, further to which Steps 3 and 4 were reached in March 2019.

The MC noted the work plan of the Q3D(R2) Maintenance EWG and was updated by the Coordinator for FDA, United States on the progress made by the group on the Q3D(R2) revision to include PDEs for cutaneous and transdermal Routes of Administration; as well as on the group's considerations to meet face-to-face in Amsterdam in June 2019.

MC Actions/Decisions:

- *The MC noted the group's request to meet for two days, and agreed that the Secretariat would look into the possibility of coordinating the Q3D(R2) Maintenance EWG meeting with the M7(R2) Maintenance EWG meeting so that they would occur back-to-back, including exploring the possibility of booking a meeting room on Friday, 7 June after the end of the ICH meeting week to accommodate a 2-day Q3D(R2) meeting on the Thursday and Friday, and to report back to the MC to support making the decision on the meeting request*[3]*;*
- *The MC noted that the Rapporteurship of the group should rotate amongst the Founding Regulatory Members as per the Maintenance Procedure described in Annex 4 of the SOP of the WGs, and that the Assembly will be invited at its meeting Amsterdam in June 2019 to approve the transition of Rapporteurship to MHLW/PMDA, Japan for the next two years from the end of the Amsterdam meeting.*

Steps 1 and 2a/b of the Q3D(R2) revision for the cutaneous and transdermal products are expected by Q2 2019.

[3] Post teleconference note dated 29 March 2019: Further to the TC, the MC confirmed approval for the Q3D(R2) Maint. EWG meeting from Thursday to Friday.

3.1.3. E2B(R3) EWG/IWG: Revision of the Electronic Submission of Individual Case Safety Reports *(Rapporteur: Dr. Misu – MHLW/PMDA, Japan; Regulatory Chair: Mr. Chen – FDA, United States)*

The MC noted the work plan of the E2B(R3) EWG/IWG and was updated by the Coordinator for MHLW/PMDA, Japan on the group's activities.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Amsterdam in June 2019.*

Sign-off on an updated Implementation Guide package is expected by June 2019.

3.1.4. E8(R1) EWG: Revision on General Considerations for Clinical Trials *(Rapporteur: Dr. LaVange – FDA, United States; Regulatory Chair: Dr. Sweeney – EC, Europe)*

The MC agreed in 2018 to initiate a communication pilot with the E8(R1) EWG to involve ICH Members whose requests to appoint experts to the EWG had not been accepted due to considerations on the size of the WG. As part of the pilot, the E8(R1) EWG shared the E8(R1) draft Technical Document prior to Step 1 with interested ICH internal Member stakeholders, and a teleconference was organised on 18 January 2019 with the E8(R1) EWG and the interested ICH internal Member stakeholders to answer questions regarding the draft Technical Document.

The MC noted the work plan of the E8(R1) EWG and was updated by the Coordinator for FDA, United States on the progress made by the group to finalize the E8(R1) Technical Document, and the group's considerations on the necessity to hold a face-to-face meeting in Amsterdam in June 2019 to review early comments received during the ongoing public consultation period, as well as to start drafting training materials and to plan for the ICH E8(R1) public stakeholder meeting.

MC Actions/Decisions:

- *The MC supported the group's request to meet for 4 days (Sunday-Wednesday) in Amsterdam in June 2019;*
- *The MC noted that the E8(R1) EWG is planning to hold a public stakeholder meeting, as per the GCP renovation plan.*

Steps 1 and 2a/b are expected electronically by March/April 2019.

An ICH E8(R1) public stakeholder meeting, organised by the E8(R1) EWG, will be held in the United States in October 2019 as per the GCP renovation plan, and seminars on ICH E8(R1), organised by ICH Members, are expected in various ICH regions from July 2019.

3.1.5. E17 IWG: Multi-Regional Clinical Trials *(Rapporteur: Dr. Dunder – EC, Europe; Regulatory Chair: Mr. Otsubo – MHLW/PMDA, Japan)*

The MC noted the work plan of the E17 IWG and was updated by the Coordinator for EC, Europe on the progress made by the group on the finalisation of the training materials.

MC Action/Decision:

- *The MC supported the group's request to meet for 3 days (Monday-Wednesday) in Amsterdam in June 2019.*

The publication of the training materials is expected by June 2019.

3.1.6. M2 EWG: Electronic Standards for the Transfer of Regulatory Information (ESTRI) *(Co-Rapporteurs: Ms. Slack – FDA, United States / Dr. Okada – MHLW/PMDA, Japan; Regulatory Chair: Dr. Jaermann – Swissmedic, Switzerland)*

The MC noted the work plan of the M2 EWG and was updated by the Coordinator for FDA, United States on the progress made by the group on the White Paper on the potential of the HL7 Fast Healthcare Interoperability Resources (FIHR) standard for ICH initiatives; on the finalisation of a Service Level Understanding for terminology list management with the E2B EWG/IWG, and on project opportunities.

MC Actions/Decisions:

- *The MC noted that the draft White Paper on the FIHR standard would be shared with the MC ahead of the meeting in Amsterdam;*
- *The MC supported the group's request to meet for 4 days (Monday-Thursday), including the request to hold a joint meeting with the E2B(R3) EWG/IWG and with the M11 EWG, and a TC with the M8 EWG/IWG ahead of or at the time of the meeting. The MC further supported inviting HL7's CTO for a 1-day face-to-face meeting with the group in Amsterdam.*

3.1.7. S11 EWG: Nonclinical Safety Testing in Support of Development of Paediatric Medicines *(Rapporteur: Dr. Brown –FDA, United States; Regulatory Chair: Dr. van der Laan – EC, Europe)*

Step 2b on the S11 draft Guideline was reached electronically in September 2018, further to which the S11 Draft Guideline was issued for public consultation ending in April 2019.

The MC noted the work plan of the S11 EWG and was updated by the Coordinator for FDA, United States on the status of comments received to-date as part of the public consultation period which will end in April 2019.

MC Action/Decision:

- *The MC supported the group's request to meet for 4 days (Monday-Thursday) in Amsterdam in June 2019.*

Steps 3 and 4 are expected by November 2019.

3.2. WGS APPROVED TO MEET IN AMSTERDAM (PROVISIONALLY APPROVED IN CHARLOTTE, NC, USA, IN NOVEMBER 2018, AND APPROVED ELECTRONICALLY ON 12 MARCH 2019)

3.2.1. E9(R1) EWG: Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses *(Acting Rapporteur: Dr. Petavy – EC, Europe; Regulatory Chair: Dr. Ando – MHLW/PMDA, Japan)*

Step 2b of the E9(R1) draft Addendum was reached electronically in August 2017, further to which the E9(R1) draft Addendum was issued for public consultation ending in May 2018.

The MC noted the work plan of the E9(R1) EWG and was updated by the Coordinator for EC, Europe on the progress made by the group towards addressing the comments received during the regional public consultation period.

MC Actions/Decisions:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 4 days (Monday-Thursday);*
- *The MC noted that in Amsterdam the Assembly will be invited to endorse the current Acting Rapporteur as Rapporteur.*

Steps 3 and 4 are expected by September 2019.

3.2.2. E11A EWG: Paediatric Extrapolation *(Rapporteur: Dr. Yao – FDA, United States)*

The MC noted the work plan of the E11A EWG and was updated by the Coordinator for FDA, United States on the progress made by the group on the E11A draft Technical Document. The MC further noted that the E11A EWG is currently divided into 3 subgroups to work on disease similarity; modelling and simulation; and statistics.

MC Action/Decision:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 4 days (Monday-Thursday).*

Steps 1 and 2a/b are expected by November 2020.

3.2.3. E14/S7B IWG: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs *(Rapporteur: Dr. Strauss – FDA, United States; Regulatory Chair: Dr. Shinagawa – MHLW/PMDA, Japan)*

The E14/S7B IWG was established in November 2018 further to the Assembly approval of the new area of work and the MC approval of the E14/S7B Concept Paper at the ICH meeting in Charlotte, NC, USA in November 2018.

The MC noted the work plan of the E14/S7B IWG and was updated by the Coordinator for FDA, United States on the progress made by the group on the development of the first stage of Q&As, as well as on the group's considerations to proceed directly to *Steps 3* and *4* without undergoing regulatory public consultation as per section 2.2.1 of the SOP of the WGs.

MC Actions/Decisions:

- *The MC agreed that a decision on whether the Q&As should proceed directly to Steps 3 and 4 without the need for public consultation would be taken by the MC when the final Q&As document is available for MC review to confirm that it does not set forth substantial new interpretations of the E14 and S7B Guidelines;*
- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 4 days (Monday-Thursday).*

Steps 3 and 4 are expected by June 2020.

3.2.4. M7(R2) Maintenance EWG/IWG: Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk *(Rapporteur: Dr. Honma – MHLW/PMDA, Japan; Regulatory Chair: N/A)*

The M7(R2) Maintenance EWG/IWG initiated work on the development of Q&As further to the Assembly approval of its revised Concept Paper at its meeting in Charlotte, NC, USA in November 2018.

The MC noted the work plan of the M7(R2) Maintenance EWG/IWG and was updated by the Coordinator for MHLW/PMDA, Japan on the progress made by the group on the M7(R2) revision; the development of the list of compounds to be considered for the second Addendum; and on the development of the Q&As document.

MC Actions/Decisions:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam. However, the number of days and the exact dates are still to be confirmed by the*

MC, in view of considerations regarding the Q3D(R2) Maintenance EWG meeting with a view to coordinate both meetings so that they would be held back-to-back[4];

- *The MC noted that the final list of compounds to be considered for the second Addendum would be shared with the MC ahead of the meeting in Amsterdam;*
- *The MC noted that the Rapporteurship of the group will rotate amongst the Founding Regulatory Members as per the Maintenance Procedure included in Annex 4 of the SOP of the WGs, and that the Assembly will be invited in Amsterdam in June 2019 to approve the transition of Rapporteurship to EC, Europe for the next two years from the end of the Amsterdam meeting.*

The final list of compounds to be considered for the second Addendum is expected to be finalised by April 2019.

Steps 1 and 2a/b for the revised M7(R2) draft Guideline (including the revised second Addendum) are expected by November 2019.

Steps 1 and 2a/b for M7(R2) Q&As are expected by November 2019.

3.2.5. M11 EWG: Clinical electronic Structured Harmonized Protocol (CeSHarP) *(Acting Rapporteur: Ms. Combs – PhRMA; Regulatory Chair: Dr. Fitzmartin – FDA, United States)*

The M11 EWG was established in November 2018 further to the MC approval of the M11 Concept Paper and Business Plan at its meeting in Charlotte, NC, USA in November 2018.

The MC noted the work plan of the M11 EWG and was updated by the Coordinator for PhRMA on the progress made by the group on the M11 draft Technical Document.

MC Actions/Decisions:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 4 days (Monday-Thursday) and hold a joint meeting with the M2 EWG;*
- *The MC noted that in Amsterdam the Assembly will be invited to endorse the current Acting Rapporteur as Rapporteur.*

Steps 1 and 2a/b are expected by July 2020.

3.2.6. Q12 EWG: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management *(Rapporteur: Ms. Boam – FDA, United States; Regulatory Chair: Ms. Kruse – EC, Europe)*

The MC noted the work plan of the Q12 EWG and the report of the Q12 interim meeting which was held in Tokyo, Japan in February 2019, and was updated by the Coordinator for FDA, United States on the progress made towards addressing the comments received during the regional public consultation period which ended in December 2018.

MC Actions/Decisions:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 5 days (Sunday-Thursday);*
- *The MC supported the group's request to hold separate pre-meetings for Industry and Regulatory Members of the Q12 EWG on Saturday at the meeting in Amsterdam; as well as the joint meeting with the Q2(R2)/Q14 EWG;*

Steps 3 and 4 are expected by June 2019.

[4] Post teleconference note dated 29 March 2019: Further to the TC, the MC confirmed approval for the M7(R2) Maint. EWG/IWG meeting from Monday to Thursday.

3.2.7. Q2(R2)/Q14 EWG: Analytical Procedure Development and Revision of Q2 (R1) Validation of Analytical Procedures *(Rapporteur: Dr. Hiyama – MHLW/PMDA, Japan; Regulatory Chair: Dr. Keire – FDA, United States)*

The Q2(R2)/Q14 EWG was established in November 2018 further to the MC approval of the Q2(R2)/Q14 Concept Paper and Business Plan at its meeting in Charlotte, NC, USA in November 2018.

The MC noted the work plan of the Q2(R2)/Q14 EWG and was updated by the Coordinator for MHLW/PMDA, Japan on the progress made by the group on the Q2(R2)/Q14 draft Technical Document. The MC further noted that the group is currently divided into 3 subgroups to work on the revision of the Q2(R1) Guideline, the development of the Q14 draft Technical Document, and on the coordination of the work between the two activities, and that the group is also liaising with the Q12 EWG in order to ensure that both Guidelines are well aligned.

MC Actions/Decisions:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 4 days (Monday-Thursday);*
- *The MC supported that the group hold a joint meeting with the Q12 EWG in Amsterdam.*

Steps 1 and 2 a/b are expected by June 2020.

3.2.8. Q13 EWG: Continuous Manufacturing of Drug Substances and Drug Products *(Rapporteur: Dr. Lee – FDA, United States; Regulatory Chair: Dr. Matsuda – MHLW/PMDA, Japan)*

The Q13 EWG was established in November 2018 further to the MC approval of the Q13 Concept Paper and Business Plan at its meeting in Charlotte, NC, USA in November 2018.

The MC noted the work plan of the Q13 EWG and was updated by the Coordinator for FDA, United States on the progress made by the group on the Q13 draft Technical Document, as well as the group's considerations on the organisation for the regulatory experts of the group of either one Continuous Manufacturing (CM) site visit or multiple regional CM site visits, between end of 2019 and early 2020, for educational purposes in support of the development of the Q13 Technical Document.

MC Actions/Decisions:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 4 days (Monday-Thursday);*
- *The MC noted that the regulatory experts of the group would keep the MC informed of their plans to make one or multiple site visits.*

Steps 1 and 2 a/b are expected by June 2020.

3.2.9. S5(R3) EWG: Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals *(Rapporteur: Dr. Waxenecker – EC, Europe; Regulatory Chair: N/A)*

Steps 2b on the S5(R3) draft Guideline was reached electronically in August 2017, further to which the S5(R3) Draft Guideline was issued for public consultation ending in March 2018.

The MC noted the work plan of the S5(R3) EWG and the Concept Paper on the Establishment of a Maintenance Procedure on the Annexes of the S5 Guideline, and was updated by the Coordinator for EC, Europe on the progress made by the group towards addressing the comments received during the regional public consultation period which ended in March 2018.

MC Actions/Decisions:

- *The MC noted that as approved electronically on 12 March 2019, the group will meet in Amsterdam for 4 days (Monday-Thursday);*

- *The MC supported a minor revision to the draft S5 Concept Paper for a Maintenance Procedure to specify that a Concept Paper would have to be submitted along with the Work Plan to support a proposal for revision, and that the revised draft S5 Concept Paper for a Maintenance Procedure would be submitted to the MC ahead of the meeting in Amsterdam in June 2019.*

Steps 3 and 4 are expected by November 2019.

3.3. WGS NOT REQUESTING TO MEET IN AMSTERDAM

3.3.1. Standing Paediatric EWG *(Rapporteur: Dr. Hirata – MHLW/PMDA, Japan; Regulatory Chair: Dr. Yao – FDA, United States)*

Further to the Assembly's decision at the ICH meeting in Geneva, Switzerland in November 2017, the Standing Paediatric EWG was established in February 2018 to act as a continuous resource available for expert consultation and guidance to WGs charged with developing new or revised Guidance which may be of relevance to paediatric drug development.

The MC was informed by the Coordinator for MHLW/PMDA, Japan that the Standing Paediatric EWG did not receive new requests for paediatric advice from WGs since the meeting in Charlotte, NC, USA in November 2018, other than from the S11 EWG, and that the group remains available for expert consultation and guidance to ICH WGs.

3.3.2. E19 EWG: Optimization of Safety Data Collection *(Rapporteur: Dr. Thanh Hai – FDA, United States; Regulatory Chair: Dr. Mol - EC, Europe)*

The MC noted the work plan of the E19 EWG and was informed by the ICH Secretariat on the progress made on the completion of *Step 1* and *Step 2a/b* endorsement.

Steps 3 and 4 are expected by June 2021.

3.3.3. E20 informal Working Group: Adaptive Clinical Trials *(Proposal from: PhRMA)*

In Charlotte, NC, USA in November 2018, the MC agreed that as of March 2019 the ICH Secretariat would issue a call for expressions of interest to nominate experts, further to which the MC would be invited to confirm the membership of the group, with a view to the group starting work on drafting the E20 Concept Paper and Business Plan by June/July 2019.

The MC was informed by the ICH Secretariat on the progress made towards the establishment of the E20 informal WG, and that the process was on track to meet the planned timeframe for the group to start work on drafting the E20 Concept Paper and Business Plan by June/July 2019.

MC Actions/Decisions:

- *The MC noted that the 3-week call for expression of interest to nominate experts to the E20 informal Working Group had been launched, with the deadline set to Tuesday, 26 March 2019;*
- *The MC noted that PhRMA, as the Member who proposed the topic, had agreed to lead the informal WG (as per section 1.2 of the SOP) and to subsequently be put forward for Rapporteurship upon establishment of the EWG (as per section 1.5.2 of the SOP), pending ICH Assembly approval.*

3.3.4. M1 PtC WG: MedDRA Points to Consider *(Rapporteur: Dr. Winter – EFPIA; Regulatory Chair: Dr. Brajovic – FDA, United States)*

The MC noted the work plan of the M1 PtC WG and was updated by the Coordinator for EFPIA on the progress made by the group on the update of the Points to Consider documents with each MedDRA release.

Release of next versions of the "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider documents" (updated for MedDRA Version 22.1) are expected in September 2019.

3.3.5. M4Q(R1) IWG: (CTD-Quality) IWG: Addressing CTD-Q-Related Questions *(Rapporteur: Dr. Schmuff – FDA, United States; Regulatory Chair: N/A)*

The Assembly approved, at the ICH meeting in Osaka, Japan, in November 2016, that instead of disbanding the M4Q(R1) IWG, the group would become dormant in case questions are received which would need to be addressed by the M4Q(R1) IWG following the implementation of the revised M4 Granularity Document.

The MC was informed by the Coordinator from FDA, United States that no questions were so far received which would need to be addressed by the M4Q(R1) IWG.

3.3.6. M8 EWG/IWG: The Electronic Common Technical Document (eCTD) *(Rapporteur: Mr. Gray – FDA, United States; Regulatory Chair: Ms. Puusaari – EC, Europe)*

The eCTD v4.0 Q&As and Specification Change Request Document v1.2, as well as the eCTD v3.2.2 Q&As and Specification Change Request Document v1.31 reached Steps 3 and 4 at the meeting in Kobe, Japan, in June 2018.

The MC noted the work plan of the M8 EWG/IWG and was informed by the Coordinator from FDA, United States that no Change Requests were received since the meeting in Kobe, Japan, in June 2018. Furthermore, the MC was updated on the M8 EWG/IWG considerations to hold a teleconference with the M2 EWG possibly ahead of or during the M2 EWG meeting in Amsterdam to discuss implications of HL7 FHIR and potential paths forward for the eCTD.

3.3.7. M10 EWG: Bioanalytical Method Validation *(Rapporteur: Dr. Ishii-Watabe – MHLW/PMDA, Japan; Regulatory Chair: Dr. Booth – FDA, United States)*

Step 2b on the M10 draft Guideline was reached electronically on 27 February 2019, further to which the M10 draft Guideline was issued for public consultation.

The MC was informed that the ICH Secretariat is in the process of soliciting ICH Regulatory Member feedback on their respective public consultation deadlines.

MC Action/Decision:

- *The MC noted that the ICH Regulatory Members were invited to communicate their respective public consultation deadlines to the Secretariat.*

Steps 3 and 4 are expected by November 2020.

3.3.8. M12 informal Working Group: Drug Interaction Studies *(Proposal from: FDA, United States)*

In Charlotte, NC, USA in November 2018, the MC agreed that as of March 2019 the ICH Secretariat would issue a call for expressions of interest to nominate experts, further to which the MC would be invited to confirm the membership of the group, with a view to the group starting work on drafting the M12 Concept Paper and Business Plan by June/July 2019.

The MC was informed by the ICH Secretariat on the progress made towards the establishment of the M12 informal WG, and that the process was on track to meet the planned timeframe for the group to start work on drafting the M12 Concept Paper and Business Plan by June/July 2019.

MC Actions/Decisions:

- *The MC noted that the 3-week call for expression of interest to nominate experts to the M12 informal Working Group had been launched, with the deadline set to Tuesday, 26 March 2019;*
- *The MC noted that the FDA, United States, as the Member who proposed the topic, had agreed to lead the informal WG (as per section 1.2 of the SOP) and to subsequently be put forward for Rapporteurship upon establishment of the EWG (as per section 1.5.2 of the SOP), pending ICH Assembly approval.*

3.3.9. Q3C(R8) Maintenance EWG: Maintenance of the Guideline for Residual Solvents *(Rapporteur: Dr. McGovern – FDA, United States; Regulatory Chair: N/A)*

The MC noted the work plan of the Q3C(R8) Maintenance EWG and was updated by the Coordinator for FDA, United States on the progress made by the group on the development of Permitted Daily Exposure (PDE) levels for the solvents 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol.

MC Action/Decision:

- *The MC noted that, although the Rapporteurship of the group should rotate amongst the Founding Regulatory Members as per the Maintenance Procedure included in Annex 4 of the SOP of the WGs, the Founding Regulatory Members were supportive that the Rapporteurship of Q3C(R8) should remain with FDA, United States for the next two years, and that consequently the Assembly will be invited to approve in Amsterdam the continued Rapporteurship by FDA, United States for the next two years.*

Steps 1 and 2a/b are expected by Q1 2019.

3.3.10. Q11 IWG: Q&As on Selection and Justification of Starting Materials for the Manufacture of Drug Substances *(Rapporteur: Mr. McDonald – EC, Europe; Regulatory Chair: Dr. Condran – Health Canada, Canada)*

The MC was informed by the ICH Secretariat on the next steps regarding the publication of the Q11 training materials on the ICH public website and noted that the Q11 IWG had now concluded its assigned work.

MC Action/Decision:

- *The MC agreed that the Q11 IWG would be disbanded following completion of its work on the training materials.*

3.3.11. S1(R1) EWG: Revision of the Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline *(Rapporteur: Dr. Sistare – PhRMA; Regulatory Chair: Dr. Van der Laan – EC, Europe)*

The MC noted the work plan of the S1(R1) EWG and was updated by the Coordinator for PhRMA on the group's progress on the review of confidential Carcinogenicity Assessment Documents (CADs) and final Study Reports (FSRs); and on drafting the revisions to the S1B Guideline.

Steps 1 and 2a/b are expected by November 2019.

3.3.12. Informal Generic drug Discussion Group (IGDG) *(Rapporteur: Dr. Tampal – FDA, United States; Regulatory Chair: Dr. Welink – EC, Europe)*

The MC was updated by the ICH Secretariat on the establishment of the IGDG.

MC Actions/Decisions:

- *The MC noted that the Regulatory Members of the MC appointed Dr. Welink from EC, Europe to the role of IGDG Regulatory Chair and that the Assembly appointed Dr. Tampal from FDA, United States to the role of IGDG Rapporteur;*
- *The MC noted that the membership of the IGDG would be confirmed at the MC interim meeting in Brussels in April 2019.*

3.3.13. Informal Quality Discussion Group (IQDG) *(Rapporteur: Mr. Nosal – PhRMA; Regulatory Chair: Ms. Kruse – EC, Europe)*

The IQDG was established in February 2019 further to the Assembly's endorsement of the Reflection Paper on Advancing Biopharmaceutical Quality Standards to Support Continual Improvement and Innovation in Manufacturing Technologies and Approaches *at its meeting in Kobe, Japan in June 2018, and to the MC approval of the IQDG remit document at its meeting in Charlotte, NC, USA in November 2018.*

The MC was updated by the Coordinator for PhRMA on the group's activities, including on its first teleconference at the end of February; the development of its first Work Plan; and on the assessment of the New Topic proposals on Quality.

MC Action/Decision:

- *The MC noted that the IQDG would provide its assessment of the New Topic proposals on Quality in April 2019.*

4. MEMBER/OBSERVER REQUESTS TO NOMINATE EXPERTS TO WGS

4.1. MEMBER REQUESTS TO NOMINATE EXPERTS TO WGS

The MC was updated by the ICH Secretariat on requests received from Members for the nomination of new experts to WGs.

MC Action/Decision:

- *The MC agreed that feedback from the Rapporteur for the M7(R2) Maintenance EWG/IWG would be solicited regarding a new expert nomination request received from a Member to see if there are concerns around the size of the M7(R2) Maintenance EWG/IWG and the impact to the efficiency of the group's operations, and that the MC would take a decision at the MC interim meeting in Brussels in April 2019.*

4.2. OBSERVER REQUESTS TO NOMINATE EXPERTS TO WGS

The MC was updated by the ICH Secretariat on the requests received from Observers for the nomination of new experts to WGs.

MC Actions/Decisions:

- *The MC noted that as per the MC decision in March 2018, the E19 EWG is currently closed to new expert nomination requests due to considerations regarding its size, and that consequently requests to appoint new experts to this group would not be approved.*
- *The MC approved the appointment of:*
  - *One Observer expert nominated by PIC/S to the M10 EWG;*
  - *One Observer expert nominated by PIC/S to the Q13 EWG;*
  - *One Observer expert nominated by EDQM to the Q13 EWG.*

5. COMMUNICATION ABOUT ICH

The MC noted the organisation of a joint public ICH meeting by FDA, United States and Health Canada, Canada on 29 April 2019; a joint public ICH meeting by MHLW/PMDA, Japan and JPMA on 17 July 2019; as well as a seminar for the ICH E8(R1) draft Guideline by MHLW/PMDA, Japan and JPMA on 25 July 2019; an ICH public meeting by MFDS, Republic of Korea in July 2019 (dates to be confirmed) and an ICH MedDRA training by MFDS, Republic of Korea in June 2019 (dates to be confirmed).

6. DATES OF TELECONFERENCES AND NEXT MEETINGS IN 2019 / 2020

Teleconferences

12 April 2019	ICH MC Policy 3
8 May 2019	ICH MC Policy 4

Face-to-Face Meetings

1-2 April 2019 (Interim meeting)	Brussels, Belgium
1-6 June 2019	Amsterdam, The Netherlands
17-21 November 2019*	Singapore
24-28 May 2020*	Vancouver, Canada (to be confirmed)
15-19 November 2020*	Europe (location to be confirmed)
31 May - 3 June 2021*	Asia (location to be confirmed)

**Note: The new meeting schedule is implemented for meetings from November 2019 onwards, with the ICH meeting week starting on Sunday.*

7. ANY OTHER BUSINESS

7.1. OBSERVER REQUEST FOR ADDITIONAL PARTICIPANT TO ASSEMBLY MEETING

The MC was informed by the ICH Secretariat about a request received from an ICH Observer for an additional participant to the Assembly meeting in Amsterdam and the justification provided by the Observer to support an exceptional second participant.

MC Action/Decision:

- *The MC agreed to discuss the request at the MC interim meeting in Brussels.*